Notice of Allowability	Application No.	Applicant(s)	
	10/041,859	HUANG ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *26 July 2006*.

2. ☒ The allowed claim(s) is/are *1,3,4,7-19,44,46,73,74,78,79,83-85,89-91 and 95*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *20060925* .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert A. Hodges on September 25, 2006.

2. The application has been amended as follows:

In the claims:

Claim 1. (Currently Amended) An isolated nucleic acid encoding a polypeptide having at least 95% sequence identity to SEQ ID NO:2, wherein said polypeptide is capable of inhibiting caspase 9.

Claim 2. (Canceled).

Claim 3. (Currently Amended) The isolated nucleic acid of claim 1, wherein the polypeptide is capable of inhibiting Bax-induced apoptosis in *Spodoptera frugipera* or *Bombyx mori* cells.

Claim 4. (Currently Amended) The isolated nucleic acid of claim 1, wherein the polypeptide is capable of inhibiting Bax-induced apoptosis in mammalian cells.

Claims 5 and 6. (Canceled).

Claim 7. (Previously Presented) An isolated nucleic acid encoding a polypeptide comprising SEQ ID NO:2.

Claim 8. (Previously Presented) An isolated nucleic acid comprising SEQ ID NO:1.

Claim 9. (Currently Amended) An isolated expression cassette comprising at least one nucleic acid operably linked to a promoter, wherein the nucleic acid encodes a polypeptide having at least 95% sequence identity to SEQ ID NO:2, wherein said polypeptide is capable of inhibiting caspase 9.

Claim 10. (Currently Amended) The isolated expression [[of]] cassette of claim 9, wherein the promoter is a constitutive promoter.

Claim 11. (Previously Presented) The isolated expression cassette of claim 9, wherein the promoter is a developmentally regulated or a tissue specific promoter.

Claim 12. (Previously Presented) The isolated expression cassette of claim 9, wherein the polypeptide comprises SEQ ID NO:2.

Claim 13. (Currently Amended) An isolated cell transformed with an expression vector comprising a nucleic acid encoding a polypeptide having at least 95% sequence identity to SEQ ID NO:2, wherein said polypeptide is capable of inhibiting caspase 9.

Claim 14. (Previously Presented) The isolated cell of claim 13, wherein the cell is a mammalian cell.

Claim 15. (Previously Presented) The isolated cell of claim 13, wherein the cell is an insect cell.

Claim 16. (Previously Presented) The isolated cell of claim 15, wherein the insect cell is a *Spodoptera frugipera* cell or a *Bombyx mori* cell.

Claim 17. (Previously Presented) The isolated cell of claim 13, wherein the cell is a plant cell.

Claim 18. (Previously Presented) The isolated cell of claim 13, wherein the cell is a yeast cell.

Claim 19. (Previously Presented) The isolated cell of claim 13, wherein the polypeptide comprises SEQ ID NO:2.

Claims 20-43. (Canceled).

Claim 44. (Currently Amended) An array comprising a nucleic acid encoding a polypeptide having at least 95% sequence identity to SEQ ID NO:2, wherein said polypeptide is capable of inhibiting caspase 9.

Claim 45. (Canceled).

Claim 46. (Currently Amended) A method of making a polypeptide having at least 95% sequence identity to SEQ ID NO:2 comprising ~~expressing in an isolated transformed~~ culturing a cell comprising an expression vector comprising a nucleic acid encoding [[a]] said polypeptide ~~having at least 95% sequence identity to SEQ ID NO:2~~, wherein said polypeptide is capable of inhibiting caspase 9.

Claims 47-72. (Canceled).

Claim 73. (Currently Amended) The isolated nucleic acid of claim [[72]] 1, wherein the polypeptide comprises [[the]] a BIR1 domain [[has]] having the amino acid sequence of residues 74 to 140 of SEQ ID NO:2, [[the]] a BIR2 domain [[has]] having the amino acid sequence of residues 182 to 249 of SEQ ID NO:2, and [[the]] a RING domain [[has]] having the amino acid sequence of residues 298 to 314 of SEQ ID NO:2.

Claim 74. (Previously Presented) The isolated expression cassette of claim 9, wherein the nucleic acid comprises SEQ ID NO:1.

Claims 75-77. (Canceled).

Claim 78. (Currently Amended) The isolated expression cassette of claim [[77]] 9, wherein the polypeptide comprises [[the]] a BIR1 domain [[has]] having the amino acid sequence of residues 74 to 140 of SEQ ID NO:2, [[the]] a BIR2 domain [[has]] having the amino acid sequence of residues 182 to 249 of SEQ ID NO:2, and [[the]] a RING domain [[has]] having the amino acid sequence of residues 298 to 314 of SEQ ID NO:2.

Claim 79. (Previously Presented) The isolated cell of claim 13, wherein the nucleic acid comprises SEQ ID NO:1.

Claims 80-82. (Canceled).

Claim 83. (Currently Amended) The isolated cell of claim [[82]] 13, wherein the polypeptide comprises [[the]] a BIR1 domain [[has]] having the amino acid sequence of residues 74 to 140 of SEQ ID NO:2, [[the]] a BIR2 domain [[has]] having the amino acid sequence of residues 182 to 249 of SEQ ID NO:2,

and [[the]] a RING domain [[has]] having the amino acid sequence of residues 298 to 314 of SEQ ID NO:2.

Claim 84. (Previously Presented) The array of claim 44, wherein the polypeptide comprises SEQ ID NO:2.

Claim 85. (Previously Presented) The array of claim 84, wherein the nucleic acid comprises SEQ ID NO:1.

Claims 86-88. (Canceled).

Claim 89. (Currently Amended) The array of claim [[88]] 44, wherein the polypeptide comprises [[the]] a BIR1 domain [[has]] having the amino acid sequence of residues 74 to 140 of SEQ ID NO:2, [[the]] a BIR2 domain [[has]] having the amino acid sequence of residues 182 to 249 of SEQ ID NO:2, and [[the]] a RING domain [[has]] having the amino acid sequence of residues 298 to 314 of SEQ ID NO:2.

Claim 90. (Previously Presented) The method of claim 46, wherein the polypeptide comprises SEQ ID NO:2.

Claim 91. (Previously Presented) The array of claim 90, wherein the nucleic acid comprises SEQ ID NO:1.

Claims 92-94. (Canceled).

Claim 95. (Currently Amended) The method of claim [[94]] 46, wherein the polypeptide comprises [[the]] a BIR1 domain [[has]] having the amino acid sequence of residues 74 to 140 of SEQ ID NO:2, [[the]] a BIR2 domain [[has]] having the amino acid sequence of residues 182 to 249 of SEQ ID NO:2, and

[[the]] a RING domain [[has]] having the amino acid sequence of residues 298 to 314 of SEQ ID NO:2.

Claims 96-106. (Canceled).

Examiner's Statement of Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance:

The prior art does not teach or fairly suggest an isolated polypeptide comprising an amino acid sequence that is at least 95% identical to the amino acid sequence of SEQ ID NO: 2, which is capable of inhibiting caspase-9 activity and capable of inhibiting Bax-induced apoptosis. Accordingly, the prior art does not teach or fairly suggest an isolated nucleic acid molecule encoding such a polypeptide, an expression cassette comprising a nucleic acid sequence encoding the polypeptide, or an isolated cell transformed with such a vector, nor does the prior art teach or fairly suggest an array comprised of such a nucleic acid molecule, or a method for making such a polypeptide comprising culturing such cells.

Furthermore, the Examiner finds no factual evidence teaching or suggesting that the disclosure would *not* reasonably enable the skilled artisan to make and use such polypeptides comprising an amino acid sequence that is at least 95% identical to the amino acid sequence of SEQ ID NO: 2, which are capable of inhibiting caspase-9 activity and capable of inhibiting Bax-induced apoptosis. This is believed the case since the disclosure describes with particularity three domains of the polypeptide of SEQ ID NO: 2, which are essential to such activities, thereby providing much of the requisite guidance and direction necessary to make functional variants of the polypeptide of SEQ ID NO: 2. See *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971) ("[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is

reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.").

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

5. Claims 1, 3, 4, 7-19, 44, 46, 73, 74, 78, 79, 83-85, 89-91, and 95 have been allowed.

6. Claims 1, 3, 4, 7-19, 44, 46, 73, 74, 78, 79, 83-85, 89-91, and 95 have been renumbered as claims 1-29, respectively.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
September 25, 2006